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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/25/2003

Charles D. Claude

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01/16/2009

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/723,137	Applicant(s) CLAUDE ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14,32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-37 is/are allowed.
- 6) ☒ Claim(s) 11-14,32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response filed 9/22/2008 has been received. Claims 11-14, 31, 32, and 34-37 are pending in this action.

Claim Rejections - 35 USC § 112

Claims 11-14, 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for block copolymers where the elastomeric polymer is polyisobutylene, polyperfluoroalkylene, polyhexafluoropentene, poly(butyl methacrylate) poly(lauryl methacrylate) polyalkylene oxide, polyalkylene oxide acrylate or a combination thereof, does not reasonably provide enablement for polymers that are not block copolymers or polymers where the elastomeric polymer is natural rubber or nylon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims fail to meet the enablement requirement when a person of ordinary skill in the art would have to perform undue experimentation to make or use the claimed invention. Undue experimentation is considered in view of the factors enumerated in MPEP 2614.01(a). All of these factors have been considered, and the most relevant are discussed below.

1. The breadth of the claims

The claims read on an implant comprising a coating, the coating comprising a polysulfone conjugated to one or more enumerated elastomeric polymers by direct

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chemical bonding. The form of the conjugate is not specified; it may include a block copolymer, a graft copolymer, a brush copolymer, or some other bonding scheme.

2. The nature of the invention

Applicants' have discovered that copolymers of polysulfones and elastomers are advantageous for coating implants.

3. The level of one of ordinary skill

The relevant art is chemistry. A chemist of ordinary skill has a bachelor degree, or an equivalent combination of education and training. See C&EN publication (consistently five times more bachelor's degrees than doctorate degrees in chemistry awarded in the United States). This is a fair assessment, because it takes into account that some chemists have more education, such as a doctorate degree; while others have less education, such as a technical or associate degree; and still others lack formal education and have only on-the-job technical training.

4. The level of predictability in the art

Copolymers of polysulfones are uncommon in the art. As such, there is no predictable way to make new copolymers.

5. The direction provided by the inventor and working examples

The inventor has shown a method of making sulfones that are end-functionalized with a group that can be used to initiate a chain polymerization in order to grow an elastomeric polymer that is polymerizable by a chain mechanism from one or both ends of the polysulfone. See examples. However, what is not shown is how to make polymer architectures where the elastomeric polymer is conjugated in a place other than

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the end of the polysulfone (such as a graft or brush architecture). Also, what is not shown is how to fix step-grown polymers to the end of the polysulfone.

6. The quantity of experimentation needed

The artisan would be able to make block copolymers of polysulfones and elastomeric polymers where the elastomeric polymer is polymerizable by a chain-growth process (such as polyolefins or PEO). However, natural rubber and nylon are not made by chain-growth processes. Thus, the artisan would have to start from scratch to determine how to make copolymers of polysulfone with either of these elastomers. Also, the artisan would not know how to make polymer architectures other than block copolymers, and would have to start the inventive process from scratch to determine how to make such materials.

Allowable Subject Matter

Claims 33 and 35-37 are allowed. Claim 11 would be allowable if amended to include the limitations of claim 32 (namely, elimination of natural rubber and nylon from the list of permissible elastomeric polymers) and amended to require that the polymeric composition comprise a block copolymer of a polysulfone (A) and an elastomeric polymer (B).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618